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PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.92)

807.92 (a):

1. *Submitter's Name:* STC Technologies, Inc.
   Address: 1745 Eaton Avenue, Bethlehem, PA 18018
   Telephone Number: (610) 882-1820
   Contact Person: R. Sam Niedbala, Ph.D., BCFE
   Date Prepared: April 25, 2000

2. *Device Name:*
   Proprietary Name: PCP Intercept™ MICRO-PLATE EIA
   Usual Name: PCP Intercept™ System
   Classification Name: Enzyme Immunoassay, PCP

3. *Device to Which Substantial Equivalence Is Claimed:*
   Roche Diagnostic Systems, Abuscreen ONLINE® kit for PCP (urine); K920935

4. *Description of Device:*

Principle of the Assay

The STC PCP Intercept™ MICRO-PLATE EIA is a competitive micro-plate immunoassay for the detection of PCP in oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device. Specimen or standard is added to an EIA well in combination with an enzyme-labeled hapten derivative. In an EIA well containing an oral fluid specimen positive for PCP, there is a competition between the drug and the enzyme-labeled hapten to bind the antibody fixed onto the EIA well. EIA wells are then washed, substrate is added, and color is produced. The absorbance measured for each well at 450 nm is inversely proportional to the amount of PCP present in the specimen or calibrator/control. Because currently there are no SAMHSA assigned cutoffs for PCP testing using oral fluid, STC recommends a cutoff of 1 ng/mL when testing oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device. This cutoff is within the limit of detection by the STC PCP Intercept™ MICRO-PLATE EIA.

KIT COMPONENTS
Anti-PCP Coated Plate – Mouse anti-PCP monoclonal antibody immobilized on a polystyrene plate supplied in dry form.
Enzyme Conjugate – Horseradish peroxidase labeled with a PCP hapten diluted in a protein matrix of bovine serum with protein stabilizers.
Substrate Reagent -- One bottle containing 3,3', 5,5' tetramethylbenzidine.
Stopping Reagent -- Each bottle contains 2 N sulfuric acid.
Pre-Buffer – One bottle containing a 250 mM Tris buffer solution.
Oral Fluid Negative Calibrator – Oral Fluid Diluent tested to be negative for PCP.
Oral Fluid Negative Control – Oral Fluid Diluent containing 0.5 ng/mL (v/v) PCP and tested by EIA.
Oral Fluid Cutoff Calibrator – Oral Fluid Diluent containing 1.0 ng/mL (v/v) PCP and tested by EIA.
Oral Fluid Positive Control – Oral Fluid Diluent containing 1.5 ng/mL (v/v) PCP and tested by EIA.

Principle of the Intercept™ DOA Oral Specimen Collection Device

Saliva is a complex mixture of parotid, submandibular, sublingual and minor salivary gland secretions mixed with mucin, bacteria, leukocytes, sloughed epithelial cells and gingival crevicular fluid. The fact that PCP is present in oral fluid following human use is well documented.[2,5]

The Intercept™ DOA Oral Specimen Collection Device was developed for the purpose of collecting oral fluid for diagnostic testing. The collection device consists of a treated absorbent cotton fiber pad affixed to a nylon stick (Collection Pad) and a preservative solution in a plastic container (Specimen Vial). The Collection Pad is impregnated with a mixture of common salts and gelatin which creates a hypertonic environment and an increased osmotic pressure wherever it contacts oral mucosal cells. The pad is

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placed in contact with the gingival mucosa (between the lower gum and cheek) which enhances the flow of mucosal transudate across the mucosal surfaces onto the absorptive cotton fibers of the pad. Following the collection period, the Collection Pad is placed into a vial containing a preservative solution which serves to inhibit the growth of oral micro-organisms recovered on the Collection Pad. The vial is sealed with a plastic cap and transported to a laboratory for processing and testing. Following processing, a fluid containing a mixture of saliva components and the preservative solution is recovered which is suitable for testing for the presence of PCP in the STC PCP Intercept™ MICRO-PLATE EIA manufactured by STC Technologies, Bethlehem, PA. Refer to the Intercept™ DOA Oral Specimen Collection Device product insert for specific instructions on the proper collection, handling and adequacy of oral fluid samples.

5. *Intended Use Statement:*
The STC PCP Intercept™ MICRO-PLATE EIA is intended for use by clinical laboratories in the qualitative determination of PCP in oral fluid collected with the Intercept™ DOA Oral Specimen Collection Device using a 1 ng/mL cutoff. **For *In Vitro* Diagnostic Use.**

The STC PCP Intercept™ MICRO-PLATE EIA provides only a preliminary analytical test result. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry/mass spectrometry (GC/MS/MS) is the preferred confirmatory method. This is a confirmation method that is currently pending SAMHSA acceptance. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.

6. *Summary of Technological Characteristics:*
The STC PCP Intercept™ MICRO-PLATE EIA is based on the principle of solid phase competitive enzyme immunoassay. This application is for the use of the STC PCP EIA as a screening tool for the detection of PCP using specimens collected with the Intercept™ DOA Oral Specimen Collection Device manufactured by Epitope, Inc., Beaverton, Oregon.

807.92 (b):

1. *Non Clinical Data:*
Analytical Sensitivity/Limit Of Detection - The Limit of Detection (LOD) was defined from the signal-to-noise ratio at the zero-drug concentration as the mean zero absorbance (A_0) minus the noise times three (LOD = A_0 - 3SD). The LOD was determined by obtaining the average absorbance value for 64 readings of blank Oral Fluid Diluent and calculating the standard deviation (SD) and 3SD of the absorbance. The absorbance value minus 3SD was then extrapolated from the curve and represents the sensitivity of the assay. The LOD was calculated to be 0.49 ng/mL.

Precision - The precision of the STC PCP Intercept™ MICRO-PLATE EIA was assessed by testing the Oral Fluid Diluent containing 0, 0.5, 1.0 and 1.5 ng/mL PCP. Intra-assay precision was determined by analyzing each level 16 times per run for 4 runs. Inter-assay precision was determined by analyzing 2 replicates for each level two times per day over a 14 day period. The results of this testing are described in the following table:

PCP (ng/mL)	Mean O.D.	Intra-Assay % CV (n=64)	Inter-Assay % CV (n=4/day, 14 days)
0	1.951	7.2	10.7
0.5	1.565	6.1	11.8
1.0	1.203	7.1	14.0
1.5	0.976	8.8	18.5

Analytical Specificity/Cross-Reactivity - The analytical specificity of an immunoassay is defined as the cross-reactivity of substances in the assay which are structurally related to the target compound.

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The cross-reactivity of structurally related compounds was calculated at several spiked concentrations in Oral Fluid Diluent. The following table indicates the apparent concentration of PCP for each substance at a concentration which cross-reacted in the assay.

Compound	Tested Concentration (ng/mL)	PCP Equivalents (ng/mL)	Cross-Reactivity (%)
Dextromethorphan	10,000	0.411	0.004
Doxylamine	10,000	0.163	0.002
Ketamine	10,000	0.380	0.004
4-OH PCP	100	1.165	1.165

The following compounds were spiked into Oral Fluid Diluent at a target concentration of 10,000 ng/mL and tested for cross-reactivity. Imipramine was found to produce a signal less than that of the Oral Fluid Cutoff Calibrator.

Acetylsalicylic Acid	Cocaine	Imipramine	Penicillin
Alprazolam	Codeine	L-Ephedrine	Pentobarbital
Amobarbital	Cotinine	L-Methamphetamine	Phenobarbital
Ampicillin	D-Amphetamine	Lidocaine	Phenylephrine
β-Phenethylamine	D-Methamphetamine	Medazepam	Phenylpropanolamine
Benzoylecgonine	Dextromethorphan	Meperidine	Procainamide
Butabarbital	Diacetylmorphine	Methadone	Procaine
Butalbital	Fenoprofen	Metroprolol	Pseudoephedrine
Caffeine	Gemfibrozil	Morphine	Quinidine
Chlordiazepoxide	Gentisic Acid	Nalorphine	Temazepam
Chlorpromazine	Glipizide	Naproxen	Δ^9-THC
Clonazepam	Hydrocodone	Niacinamide	Theophylline
Chlorazepate	Hydromorphone	Norchlordiazepoxide	Zomepirac
Cocacthylene	Ibuprofen	Nordiazepam	

It is possible that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

2. *Clinical Data:*

The clinical accuracy of the STC PCP Intercept™ MICRO-PLATE assay was determined from specimens collected from a random population. The cutoffs for EIA and GC/MS/MS were 1.0 ng/mL PCP and 0.5 ng/mL, respectively, for oral fluid specimens. The cutoff for EIA and GC/MS was 25 ng/mL for urine specimens.

A total of 438 oral fluid and urine specimen pairs were obtained from a drug testing laboratory. All samples were tested by EIA. Of the 438 samples tested, all urine and oral fluid samples that were positive by EIA were confirmed by GC/MS for urine and by GC/MS/MS for oral fluid. In addition, 59 oral fluid samples that were negative by EIA were also tested by GC/MS/MS. The oral fluid and urine results compared as follows:

GC/MS/MS of Intercept™ Specimens
(0.5 ng/mL cutoff)

STC Intercept™ EIA (1.0 ng/mL cutoff)	+	-
+	8	1
-	2	102

% Agreement = 97.3%

Urine EIA
(25 ng/mL cutoff)

STC Intercept™ EIA (1.0 ng/mL cutoff)	+	-
+	8	1
-	2	427

% Agreement = 99.3%

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3. *Conclusions:*

A comparison of the performance data for the new device vs. the predicate device is given below:

1. Limit of Detection

Assay	LOD
STC PCP Intercept™ MICRO-PLATE EIA	0.49 ng/mL
Roche Abuscreen ONLINE®	< 5 ng/mL

2. Precision

Assay	Intra-Assay % CV Range	Inter-Assay % CV Range
STC PCP Intercept™ MICRO-PLATE EIA	6-9	11-19
Roche Abuscreen ONLINE®	3-7	3-10

3. Cross-Reactivity

Compound	% Cross Reactivity	
	Oral Fluid	Urine
β-Phenethylamine	Not Detected	< 0.05
4-OH PCP	1.165	Not Tested
d,l-Ephedrine	Not Tested	< 0.05
d-Ephedrine	Not Tested	< 0.05
d-Methamphetamine	Not Detected	< 0.05
d-Phenylpropanolamine	Not Tested	< 0.05
d-Pseudoephedrine	Not Tested	< 0.05
Dextromethorphan	0.004	0.01
Diphenhydramine	Not Tested	< 0.05
Doxylamine	0.002	Not Tested
Ketamine	0.004	Not Tested
l-Amphetamine	Not Tested	< 0.05
l-Ephedrine	Not Detected	< 0.05
l-Methamphetamine	Not Detected	Not Tested
l-Norpseudoephedrine	Not Tested	< 0.05
l-Pseudoephedrine	Not Tested	< 0.05
MDA	Not Tested	< 0.05
MDMA	Not Tested	< 0.05
p-Hydroxyamphetamine	Not Tested	< 0.05
Phentermine	Not Tested	< 0.05
Phenylephrine	Not Detected	Not Tested
Phenylpropanolamine	Not Detected	< 0.05
Procaine	Not Detected	< 0.05
Pseudoephedrine	Not Detected	Not Tested
Thienylcyclohexylpiperidine (TCP)	Not Tested	64
Tyramine	Not Tested	< 0.05

6. References

(1) "Urine Testing for Drugs of Abuse", National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.

R Sam Niedbala

R. Sam Niedbala, Ph.D., BCFE
Chief Science Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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R. Sam Niedbala, Ph.D., BCFE
Chief Science Officer
STC Technologies, Inc.
1745 Eaton Avenue
Bethlehem, Pennsylvania 18018-1799

Re: K000399
Trade Name: STC PCP Intercept™ MICRO-PLATE EIA
Regulatory Class: II
Product Code: LCM
Dated: April 4, 2000
Received: April 14, 2000

Dear Dr. Niedbala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K000399

Device Name: STC PCP INTERCEPT™ MICRO-PLATE EIA

Indications For Use:

The STC PCP Intercept™ MICRO-PLATE EIA is intended for use by clinical laboratories in the qualitative determination of PCP in oral fluid collected with the Intercept™ Drugs of Abuse (DOA) Oral Specimen Collection Device. FOR *IN VITRO* DIAGNOSTIC USE.

The STC PCP Intercept™ MICRO-PLATE EIA provides only a preliminary analytical test result. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry/mass spectrometry (GC/MS/MS) is the preferred confirmatory method. This is a confirmation method that is currently pending SAMHSA acceptance. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000399

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

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